510(K) SUMMARY

JUL 1 2 2013

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(K) number is: K131227

1. **Submitter:**
   Caresono Technology Co., Ltd.
   4th Floor, No.11 Building Initiating Zone, Instruments and Meters Industry Base, Near Port Industry Zone, Dandong, Liaoning 118009, P.R. China

2. **Contact Person:**
   Mr. Yang Long
   Chief Operating Officer
   Shenzhen Hlongmed Biotech Co., Ltd.
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   E-mail: yanglong@hlongmed.com

3. **Date Prepared: June 2, 2013**

4. **Device Information**
   Device Name: PadScan HD series Bladder Scanner
   Models: PadScan HD 5, PadScan HD 3
   Common Name: Diagnostic Ultrasound System with Accessories
   Regulatory Class: II
   Classification Name and Product Code:
   21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)
   21 CFR 892.1570 Diagnostic Ultrasonic Transducer (90-ITX)

5. **Predicate Device**
   Manufacturer: Mcube Technology Co., Ltd.
   Device: CUBEscan BioCon-700
   510(k) Number: K111021 (Decision Date-April 27, 2011)

6. Intended Use

The PadScan HD series Bladder Scanner projects ultrasound energy through the lower abdomen of the patient to obtain images of the bladder which is used to calculate bladder volume noninvasively. The PadScan HD series Bladder Scanner is intended to be used only by qualified medical professionals.

7. Device Description:

The PadScan HD series Bladder Scanner manufactured by Caresono Technology Co., Ltd. provides real-time ultrasound imaging and measuring, and also provides non-invasive volume measurement of the bladder. During image scanning, multiple 2D plane ultrasonic images are acquired in several seconds.

It features:

- Expert operating mode and Easy operating mode.
- Correct, reliable, fast, and simple operation.
- Printouts of ultrasound images with many parameters.
- Portable
- Combined power supply with AC adapter and a built-in battery.

8. Indications for Use

The PadScan HD series Bladder Scanner is B-mode pulsed-echo ultrasound device. It is intended as a portable battery-operated device. The PadScan HD series Bladder Scanner projects ultrasound energy through the lower abdomen of the patient to obtain images of the bladder which is used to calculate bladder volume noninvasively. The PadScan HD series Bladder Scanner is intended to be used only by qualified medical professionals.

9. Contraindications

Do not use the PadScan HD series Bladder Scanner on following cases:

a) Fetal use or pregnant patients

b) Patients with ascites

c) Patients with open or damaged skin

d) Wounds in the suprapubic region

10. Compatible with predicate device:

The PadScan HD series Bladder Scanner is substantially equivalent in intended use and operation to following predicate devices:

K111021 CUBEscan Diagnostic Ultrasound System and Accessories

The ultrasound power transmitted from the device is not user adjustable,

and PadScan HD series Bladder Scanner is Track 1 System and meets the FDA's pre-amendment acoustic output limits. So as the predicate devices are. Although there are some differences such as resonant frequency, power source and display screen, there is no significant differences in technological characteristics that affecting the safety and efficiently. These are evaluated by safety test and acoustic output test.

Item	Proposed Device	Predicate Device
Trade Name	PadScan HD series Bladder Scanner	CUBEscan BioCon-700
Model	PadScan HD 5, PadScan HD 3	BioCon-700
510(K) Submitter	Caresono Technology Co., Ltd.	Mcube Technology Co., Ltd.
510(K) Number	--	K111021
Classifications Name & Citations	21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO) 21 CFR 892.1570 Diagnostic Ultrasonic Transducer (90-ITX)	21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO) 21 CFR 892.1570 Diagnostic Ultrasonic Transducer (90-ITX)
Indications for Use	The PadScan HD series Bladder Scanner is B-mode pulsed-echo ultrasound device. It intended as a portable battery-operated device. The PadScan HD series Bladder Scanner projects ultrasound energy through the lower abdomen of the patient to obtain images of the bladder which is used to calculate bladder volume noninvasively. The PadScan HD series Bladder Scanner is intended to be used only by qualified medical professionals.	The BioCon-700 is a B-mode pulsed-echo ultrasound device. The BioCon-700 is intended as a portable battery-operated device. The BioCon-700 projects ultrasonic energy through the abdomen of the patient obtaining images of the bladder in order to calculate the urine volume non-invasively BioCon-700 is intended to be used by a qualified medical professional. Contraindications for the BioCon-700 are fetal use and use on pregnant patients.

Item	Proposed Device	Predicate Device
Contraindications	Do not use the PadScan HD series Bladder Scanner on following cases: a) Fetal use or pregnant patients. b) Patients with ascites. c) Patients with open or damaged skin. d) Wounds in the suprapubic region	Do not use the BioCon-700 on following cases: a) Fetal use or pregnant patients. b) Patients with ascites. c) Patients with open or damaged skin. d) Wounds in the suprapubic region.
Modes of operation	B mode	B mode
System Characteristics	- Portable - LCD Display - Thermal Printer - Power source: Battery or AD-DC adapter	- Portable - LCD Display - Thermal Printer - Power source: Battery or AD-DC adapter
Display	PadScan HD5: 8" TFT-LCD PadScan HD3: 7" TFT-LCD	7" TFT LCD
Controls for Change of acoustic output during scan	No	No
Transducer Type	Mechanical Sector Probe	Mechanical Sector Probe
Measurement localization	Abdomen	Abdomen
Transducer Resonant Frequency	2.5 MHz	2.6 MHz
Number of elements	1	1
Sector Angle	120 degrees	120 degrees
No. of Scan Planes	12	12
FDA Limits	Track 1	Track 1
Product Safety Certification	IEC 60601-1:2005 + CORR.1(2006) + CORR.2(2007)	UL 60601 -1, 1st Edition CAN/CSA-C22.2 No. 601.1 -M90, 2005

Item	Proposed Device	Predicate Device
	IEC 60601-2-37:2007	EN 60601-2-37
EMC Compliance	IEC 60601-1-2	EN 60601-1-2
Patient Contacting Material	Plastic, PE (Skin Contact)	Plastic, PC (Skin Contact)
Range	- Bladder volume range: 0-999ml - Accuracy: ±15%, ±15ml	- Bladder volume range: 0-999ml - Accuracy: ±15%, ±15ml (0-999ml)
Classification of protection against electric shock	- Class II equipment - Type B equipment	- Class II equipment - Type BF equipment
Real-time scanning	Yes (Pre-scan)	Yes (Pre-scan)
PC S/W function	Data Review Data Printing	Data Review Data Printing
PC Data Upload	Using USB flash disk	Using SD card
Power	AC/DC Adapter: Input: AC100-240V, 50/60Hz, Output: DC14V±0.5V Battery: Li-ion rechargeable	AC/DC Adapter: Input: AC 100-240V, 50-60Hz Output: DC 9Vdc, 3A Battery: Li-ion rechargeable

Caresono Technology Co., Ltd. believes that the PadScan HD series Bladder Scanner is substantially equivalent to the CUBEscan BioCon-700 of Mcube Technology Co., Ltd.

11. Safety, EMC and Performance Data:

Safety:

Electrical, mechanical, environmental safety and performance data demonstrates that the device is in compliance with IEC 60601-1:2005 and IEC 60601-2-37:2007.

EMC:

Electromagnetic Compatibility data demonstrates that the device is in compliance with IEC 60601-1-2:2007.

Performance:

The PadScan HD series Bladder Scanner have been tested as Track 1 device per the FDA Guidance document "Information for Manufactures Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued in September 2008. The acoustic output is measured and calculated per NEMA UD 2:2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.

Biocompatibility:

The Biocompatibility testing conducted in according with standard Biocompatibility ISO 10993-5:2009 and ISO 10993-10:2010.

12. Conclusion:

The PadScan HD series Bladder Scanner was evaluated with safety (IEC 60601-1:2005 and IEC 60601-2-37:2007), EMC (IEC 60601-1-2:2007), Biocompatibility (ISO 10993-1:2010, ISO 10993-5:2009, ISO 10993-10:2010) and Acoustic Output (NEMA UD2:2004).

The conclusions drawn from testing of the PadScan HD series Bladder Scanner demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 12, 2013

Caresono Technology Co., Ltd.
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

Re: K131227
Trade/Device Name: PadScan HD series Bladder Scanner, Models: PadScan HD 5 and PadScan HD 3
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: June 17, 2013
Received: June 21, 2013

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131227

Device Name: PadScan HD series Bladder Scanner

Indications for Use:

The PadScan HD series Bladder Scanner is B-mode pulsed-echo ultrasound device. It is intended as a portable battery-operated device. The PadScan HD series Bladder Scanner projects ultrasound energy through the lower abdomen of the patient to obtain images of the bladder which is used to calculate bladder volume noninvasively. The Pad Scan HD series Bladder Scanner is intended to be used only by qualified medical professionals.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K131227

Diagnostic Ultrasound Indications for Use Form

System: PadScan HD 3 Bladder Scanner

Transducer: N2

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthaimic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other(Bladder)	N						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N=new indication; P= previously cleared by FDA; E=added under this appendix

Indications for Use

Diagnostic Ultrasound Indications for Use Form

System: PadScan HD 5 Bladder Scanner

Transducer: N2

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other(Bladder)	N						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N=new indication; P= previously cleared by FDA; E=added under this appendix

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) K131227

Indications for Use